REMARKS

Response to Restriction Requirement

The Office Action required restriction to one of Groups I-X, provided *infra*, which are purportedly distinct inventions under 35 U.S.C. § 121. The Office Action requires that Applicants elect one of the following ten (10) allegedly distinct inventions:

Groups I-X are as follows:

Group I: Claims 1-14, drawn to method of and agent for treating a disease associated with decreased expression of AOP-1 gene or AOP-1, classified in class 514, subclass 44 or 2.

Group II: Claims 15-16, drawn to diagnostic method for a disease associated with decreased expression of AOP-1 gene, classified in class 435, subclass 4.

Group III: Claims 15-16 drawn to diagnostic method for a disease associated with decreased expression of AOP-1, classified in class 435, subclass 4.

Group IV: Claims 17-18, drawn to diagnostic kit for disease associated with decreased expression of AOP-1 gene, classified in class 435, subclass 4.

Group V: Claims 17-18, drawn to diagnostic kit for disease associated with decreased expression of AOP-1, classified in class 435, subclass 4.

Group VI: Claims 19-20, drawn to non-human transgenic animal suitable for the use of a pathologic model of a disease associated with decreased expression of AOP-1 gene or AOP-1, classified in class 800, subclass 13.

Group VII: Claims 21-22, drawn to a transformed tissue or cell suitable as a model of a disease associated with decrease expression of AOP-1 gene or AOP-1, classified in class 435, subclass 4.

Group VIII: Claim 23, drawn to a method for screening a material enhancing the expression, production, or function of AOP-1 using a transgenic animal tissue or cell model, classified in class 800, subclass 3.

Group IX: Claims 24-28, drawn to method of screening a material enhancing AOP-1 expression comprising contacting an in vitro expression system, a report gene expression system, a AOP-1 or target molecule to determine transcript expression levels, protein or target molecule levels, classified in class 435, subclass 375.

Group X: Claims 29-32, drawn to method of screening a material enhancing AOP-1 comprising contacting with AOP-1 or target molecule of AOP-1 to determine the antioxidant or peroxynitrite scavenging activity of AOP-1, classified in class 435, subclass 375.

Applicants hereby provisionally elect Group I, which covers claims 1-14, drawn to, according to the Office Action, a method of and agent for treating a disease associated with decreased expression of AOP-1 gene or AOP-1, **with traverse**, and respectfully request reconsideration of the restriction requirement in view of the following remarks. Applicants also provisionally elect chronic heart failure, **with traverse**, in response to the species requirement of Claim 7. Applicants moreover reserve the right to file divisional application(s) directed to non-elected subject matter.

Applicants respectfully urge that the Restriction Requirement is improper, as it does not establish that searching all the inventions would constitute an undue burden on the USPTO. Accordingly, Applicants submit that the Restriction Requirement is improper and should be withdrawn or at least modified.

According to the MPEP, when claims can be examined together without undue burden, the USPTO must examine the claims on the merits even though they are directed to independent and distinct inventions. *See* MPEP at § 803, 8th Ed., Rev. No. 4. In establishing that an "undue burden" would exist for co-examination of claims, the USPTO must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the USPTO must show that the restricted groups have a separate classification, acquired a separate status in the art, or that searching would require different fields of search. *See* MPEP at § 808.02, 8th Ed., Rev. No. 4.

Applicants submit that it would not constitute an undue burden to examine the inventions of Group I, II, III, IV, and V together. The inventions of Groups I-V, while patentably distinct from each other, are related to each other by subject matter, i.e., the relationship between decreased expression of AOP-1 gene or AOP-1 and specific diseases. The search within each of Groups I-V would overlap because a search of disease associated with the decreased expression of AOP-1 gene or AOP-1 would necessarily be conducted in the same field of search as methods of diagnosing and treating such diseases. Accordingly, it would not constitute an undue burden to examine Groups I, II, III, IV, and V together.

Applicants further submit that it would not constitute an undue burden to examine the inventions of Groups II, III, IV and V together. The inventions in Groups II-V each relate to a method or means of determining the expression level of AOP-1 gene or AOP-1 and thus a search

of Groups II-V would necessarily overlap. Indeed, Applicants note that Groups II-V are all classified in class 435, subclass 4, demonstrating that they have not attained recognition in the art as separate subject matter or a separate field of search. The MPEP makes clear that if inventions are classified together, the Examiner must make an additional showing in order to require restriction:

> Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

See MPEP § 809, 8th Ed., Rev. No. 4. Applicants respectfully submit that the Examiner has not made this additional showing and therefore respectfully requests that Groups II-V be examined together. Alternatively, Applicants request that at least Groups II and IV, relating to a method or means of determining the expression level of AOP-1 gene, be examined together and Groups III and V, relating to a method or means of determining the expression level of AOP-1, be examined together.

Applicants also submit that it would not constitute an undue burden to examine the diseases of claim 7 together. The search of each of the disclosed diseases (chronic heart failure, ischemic heart disease, rheumatoid arthritis, neurodegenerative disease, hepatic disease, and renal failure) would be narrowly focused on the decreased expression of AOP-1 gene and AOP-1 in association with each disease. This narrowly focused search within each disease would not impose a serious burden on the Examiner. Accordingly, Applicants respectfully request that the species restriction requirement be withdrawn.

In view of the above remarks, it is respectfully requested that the Restriction Requirement be withdrawn and that all claims in Groups I, II, III, IV, and V be allowed to be prosecuted in the same patent application. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicants reaffirm the election with traverse of claims 1-14 (Group I) and chronic heart failure.

CONCLUSION

In view of the above remarks, early notification of a favorable consideration is respectfully requested.

A check is enclosed in the amount of $1,590.00, which covers the four-month extension of time fee. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to **Deposit Account No. 50-0206**.

Respectfully submitted,

Dated: June 12, 2006 By: _____

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